Remarks

The Application has been reviewed in light of the Official Action of October 10, 2006. Claims 18, 19, 52, 53, and 58 have been amended. Claims 63-69 are new. Claims 18-21 and 46-69 are pending in the Application.

No new matter is introduced by the amendments. The amendments correspond to matter disclosed in the specification and examples.

The Examiner rejected claims 19, 48, 49, 52, 53, 56, 58 and 60-62 under 35 U.S.C. 112 as being indefinite.

With respect to claims 19, 53, and 58, Applicants have amended these claims to address these rejections.

With respect to claim 52, Applicants request that the Examiner reconsider this rejection. Paragraph [0031] of the Application states that "The term "oil cake" refers to the refuse of flax seed, cotton seed, or other vegetable substance from which oil has been expressed, compacted into a solid mass, and used as food, for manure, or for other purposes. The term further refers to suitable vegetable substances such as soybean flower, linseed oil cake, cottonseed oil cake, peanut oil cake, safflower oil cake, coconut oil cake, palm oil cake, sesame oil cake, sunflower oil cake, rapeseed oil cake, kapok oil cake, mustard seed oil cake, and the like." Since Applicants are entitled to serve as their own lexicographer, Applicants respectfully submit that claim 52 is not indefinite.

The Examiner rejected claims 19, 21, 46-49 and 61 under 35 U.S.C. 101 as being directed to non-statutory subject matter. Applicants respectfully request that the Examiner reconsider this rejection in light of the fact that claim 18 has been amended to require a "nutraceutical composition comprising a glucosamine component in an effective amount such that, when administered to a mammal, the nutraceutical composition is effective to improve fertility." Since claims 18, 19, 48 and 49 require a composition and amount, Applicants respectfully submit that these claims are not directed to a product of nature. Claim 61 also does not claim a product of nature because this claim re-

quires a composition with a glucosamine component and a nutrient component with relative parts by weight. With respect to claims 21, 46 and 47, these claims are not products of nature but functional requirements of the nutraceutical composition. Based on the foregoing, Applicants respectfully submit that these claims are not directed to a product of nature.

The Examiner rejected claims 18-21 and 46-49 under 35 U.S.C. 102(b) as being anticipated by Rovati, Schleck et al., Maier et al. and Sherman et al. The Examiner rejected claims 18-21, 46-51, 57-59, 61 and 62 under 35 U.S.C. 102(e) as being anticipated by Watson. The Examiner rejected claims 18-21, 46-51, 53, 58, 61 and 62 under 35 U.S.C. 102(e) as being anticipated by Menard. The Examiner rejected claims 18-20, 46-49, 58, 61 and 62 under 35 U.S.C. 102(b) as being anticipated by Allan. The Examiner rejected claims 18, 21, 46-49, 58, 61 and 62 under 35 U.S.C. 102(e) as being anticipated by D'Abramo. The Examiner rejected claims 18, 21, 46-53, 58 and 60-62 under 35 U.S.C. 102(e) as being anticipated by Meisner. The Examiner rejected claims 18, 20, 21, 46-51 and 58 under 35 U.S.C. 102(b) as being anticipated by Abe et al.

Applicants respectfully request that the Examiner reconsider the rejection because claim 18 as amended requires a nutraceutical composition with "a glucosamine component base and at least one nutrient component; wherein the glucosamine component is in an effective amount ... to improve fertility."

Further, Applicants submit that claim 64 is not anticipated by these references because this claim requires a nutraceutical composition with "a glucosamine component and at least one nutrient component; wherein the glucosamine component and the at least one nutrient component are in an effective proportion and an effective amount... to improve fertility."

Still further, Applicants submit that claim 69 is not anticipated by these references because this claim requires a nutraceutical composition with "a glucosamine component and at least two nutrient components selected from a group consisting of an oil cake component, an acid component, a mineral component, a vitamin component, and a functional food component; wherein the glucosamine component and the at least two

nutrient components are in effective proportion and effective amount... to improve fertility."

An "effective amount" places a functional limitation on the claimed composition and is determined in light of applicant's specification. Geneva Pharmaceuticals Inc. v. GlaxoSmithKline PLC, 68 USPQ2d 1865, 1873 (Fed. Cir. 2003). The Application discloses that the glucosamine component is the base of the nutraceutical composition. (par. [0050]). Further, the Application discloses that the glucosamine component is the most prominent component relative to any other component in the nutraceutical composition. (compare par. [0051] to pars. [0053], [0055], [0061], [0068]; see also par. [0082] and [0083]). In order to anticipate, a cited reference must disclose a range that is sufficiently specific. MPEP §2131.03; Atofina v. Great Lakes Chemical Corp., 78 USPQ2d 1417, 1423 (Fed. Cir. 2006).

Watson discloses the use of N-acetyl glucosamine in a probiotic formulation to restablish beneficial bacteria in the body's intestinal tract. (Abstract). However, the disclosed formulation incorporates N-acetyl glucosamine as a minority component. Further, Watson does not disclose that the N-acetyl glucosamine is in an effective amount to improve fertility. Still further, Watson does not disclose that the N-acetyl glucosamine forms the base of the formulation with at least one nutrient component or that the N-acetyl glucosamine and any other component are in effective proportion and effective amount to improve fertility. As a result, Watson does not anticipate claims 18, 64 or 69.

Menard et al. discloses a composition for treating degenerative joint disease that incorporates glucosamine. (Abstract). However, Menard et al. discloses that glucosamine is incoporated with linoleic acid and asdcorbic acid over a broad range. (col. 4-5 l. 66-4). Further, the preferred embodiment indicates that glucosamine is in equal contribution to the composition as linoleic acid. Also, Menard et al. does not disclose that the glucosamine is in an effective amount to improve fertility. Still further, Menard et al. does not disclose that the glucosamine forms the base of the formulation with at least one nutrient component or that the glucosamine and any other component are in effec-

tive proportion and effective amount to improve fertility. As a result, Menard et al. does not anticipate claims 18, 64 or 69.

Maier discloses an effervescent preparation that includes glucosamine sulphate. (Abstract). However, all examples in Maier disclose that the glucosamine sulphate is the minority component to many components in the prepartation. Further, Maier does not disclose that the glucosamine sulphate is in an effective amount to improve fertility. Still further, Maier does not disclose that the glucosamine sulphate forms the base of the formulation with at least one nutrient component or that the glucosamine sulphate and any other component are in effective proportion and effective amount to improve fertility. As a result, Maier does not anticipate claims 18, 64 or 69.

Allan discloses a composition that contains D-chiro-inositol. This composition can include D-chiro-inositol and glucosamine. (col. 4 l. 44-53). However, Allan only provides examples in which the amount of D-chiro-inositol is described. Allan does not provide any indication as to the amount of glucosamine, if any, that is incorporated in the composition. Further, Allan does not disclose that the glucosamine is in an effective amount to improve fertility. Still further, Allan does not disclose that the glucosamine forms the base of the formulation with at least one nutrient component or that the glucosamine and any other component are in effective proportion and effective amount to improve fertility. As a result, Allan does not anticipate claims 18, 64 or 69.

Rovati discloses a process for generating pure glucosamine sulphate and glucosamine hydroiodide. (Abstract). However, Rovati does not disclose a nutraceutical composition. Further, Rovati does not disclose that the glucosamine is in an effective amount to improve fertility. Still further, Rovati does not disclose that the glucosamine forms the base of a formulation with at least one nutrient component or that the glucosamine and any other component are in effective proportion and effective amount to improve fertility. As a result, Rovati does not anticipate claims 18, 64 or 69.

Sherman et al. discloses a method in which poly-NAG is administered to treat osteoarthritis in the range of 100 to 1,000 mg per day. (Abstract, col. 6 l. 40). However, Sherman et al. does not disclose that the poly-NAG is in an effective amount to improve

fertility. Further, Sherman et al. does not disclose that the poly-NAG forms the base of a formulation with at least one nutrient component or that the poly-NAG and any other component are in effective proportion and effective amount to improve fertility. As a result, Sherman et al. does not anticipate claims 18, 64 or 69.

Schleck et al. discloses a composition that only contains glucosamine sulfate metal chloride. (Abstract). However, Schleck et al. does not disclose that the glucosamine sulfate metal chloride is in an effective amount to improve fertility. Further, Schleck et al. does not disclose that the glucosamine sulfate metal chloride forms the base of a formulation with at least one nutrient component or that the glucosamine sulfate metal chloride and any other component are in effective proportion and effective amount to improve fertility. As a result, Schleck et al. does not anticipate claims 18, 64 or 69.

D'Abramo discloses a diet product for the culture of larval fish and crustaceans. (Abstract). In table 4, D'Abramo discloses that glucosamine can be incorporated as a tiny fraction of the overall composition. However, D'Abramo does not disclose a nutraceutical composition. Further, D'Abramo does not disclose that the glucosamine is in an effective amount to improve fertility. Still further, D'Abramo does not disclose that the glucosamine forms the base of a formulation with at least one nutrient component or that the glucosamine and any other component are in effective proportion and effective amount to improve fertility. As a result, D'Abramo does not anticipate claims 18, 64 or 69.

Meisner discloses an ascorbic acid-based composition to treat skin that is utilized in topical form. (Abstract). Meisner discloses that the composition can include glucosamine at 5-20% (w/v). However, Meisner does not disclose a nutraceutical composition. Further, Meisner does not disclose that the glucosamine is in an effective amount to improve fertility. Still further, Meisner does not disclose that the glucosamine and any other component are in effective proportion and effective amount to improve fertility. As a result, Meisner does not anticipate claims 18, 64 or 69.

Abe et al. discloses an acqeous suspension of copper N-succinyl clucosamte that was injected in to rabbits. However, Abe et al. does not disclose a nutraceutical composition. Further, Abe et al. does not disclose that the glucosamine is in an effective amount to improve fertility. Still further, Abe et al. does not disclose that the glucosamine forms the base of a formulation with at least one nutrient component or that the glucosamine and any other component are in effective proportion and effective amount to improve fertility. As a result, Abe et al. does not anticipate claims 18, 64 or 69.

Applicants also note that an alternative rejection under 35 U.S.C. 103(a) would also be improper because the claimed invention is not obvious over the cited references. In order for the claimed invention to be obvious over the prior art, there must be some suggestion or motivation in the cited references to modify or combine the references in accordance with the claimed invention. *See,* MPEP §2143*; In re Mills*, 916 F.2d 680, 682, 16 USPQ2d 1430, 1432 (Fed. Cir. 1990). Further, the prior art references must teach or suggest all of the claim limitations. *See* MPEP §2143.

As noted by the Examiner all references do not disclose a nutraceutical composition in an effective amount to improve fertility. Thus, these references do not provide motivation to provide such an embodiment. Also, any combination of these references would still lack this feature.

Further, Rovati, D'Abramo, Meisner, and Abe et al. all do not disclose a nutraceutical composition. None of these references disclose nor fairly suggest that the embodiments in these references could be incorporated in a nutraceutical composition. Also, none of these references suggest that the formulations disclosed could be applicable to the purposes identified in any other cited reference. As a result, one skilled in the art would not be motivated to modify these references or combine them with the cited references to provide for a nutraceutical composition as claimed in claims 18, 64 and 69.

Still further, since these references do not disclose nor fairly suggest the limitations of claims 18, 64 and 69, nor that the formulations disclosed in any reference could

further the objectives of another reference, one skilled in the art would not be motivated to modify or combine the references in accordance with these claim limitations.

In view of the foregoing remarks, it is respectfully submitted that all of the claims currently pending in the application are in condition for allowance. Reconsideration and notice to that effect is earnestly requested.

Respectfully submitted,

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